REMARKS

In order to emphasize the patentable distinctions of applicant's invention over the art applied, claims 1, 13, and 14 have been amended to call for a sponge that comprises three substantially spherical radiopaque markers that are closely grouped and proximate to one another. As a result of this configuration of the markers, an x-ray image of the sponge includes a distinctive, visually recognizable shape produced by the x-ray absorption of the radiopaque marker elements.

Support for the amendment of claims 1, 13, and 14 is provided by the specification, particularly at page 15, lines 22-23, and Fig. 10 therein described. Claim 7 is canceled herewith to expedite prosecution. Claims 8-10, 12, and 15-16 were previously canceled.

Applicant's invention, as defined by remaining claims 1-6, 11, 13-14, and 17-19, as amended, provides in one aspect a surgical sponge comprising three substantially spherical radiopaque markers, the markers being closely grouped and proximate to one another. Advantageously, this allows for a distinctive, visually recognizable shape in any direction when the sponge is exposed to an X-ray machine, since the imprint of the three closely grouped spheres is detectable in any direction.

The surgical sponge disclosed by present claims 1-6, 11, 13-14, and 17-19 includes three closely proximate substantially spherical radiopaque markers – making their detection instantly recognizable, and does not even require the careful scrutiny of a trained radiologist to detect. This "signature" created by the

grouping of three substantially spherical markers is an instantly recognizable indication that there is a retained sponge inside the patient. By way of comparison, the radiopaque markers taught by the prior art can easily be overlooked or even mistaken for something else because they do not consist of a unique shape or design. Therefore, unlike the prior art surgical sponges, applicant's surgical sponge, as defined by present claims 1-6, 11, 13-14, and 17-19 is readily and reliably detectable if inadvertently left in the surgical wound. As a result, the retained sponge can be removed by a surgical procedure that can be carried out quickly. Quick removal, in turn, virtually precludes the extensive discomfort, trauma, and possibly fatal consequences that might otherwise ensue before the problem is diagnosed.

Claim Rejections – 35 USC § 103

Claims 1-7 and 17 were rejected under 35 USC 103(a) as being unpatentable over Sirimanne et al. (US 6,371,904; hereinafter "Sirimanne"). In view of the cancellation of claim 7, this rejection will be addressed with respect to remaining claims 1-6 and 17.

Sirimanne discloses subcutaneous cavity marking devices and methods. More particularly, upon insertion into a body, the cavity marking device and method enable one to determine the center, orientation, and periphery of the cavity by radiographic, mammographic, echogenic, or other non-invasive imaging techniques. Also, the device contains a bioabsorbable or non-bioabsorbable marker. The device may be combined with various substances

enhancing the radiopaque, mammographic, or echogenic characteristics of the marker or the body allowing it to be observed by any non-invasive imaging techniques. This is further a method of marking a subcutaneous cavity using a bioabsorbable material and a bioabsorbable or non-bioabsorbable marker in conjunction with the material. The method may additionally combine any of the features as described with the device.

Regarding claims 1-7, the Examiner has argued that Sirimanne teaches a surgical sponge (110) comprising three radiopaque markers (150, 154, 156), one of which (150) is a distinctive spherical shape, the markers (150, 154, 156) disposed in a substantially fixed relationship (col. 7, lines 44-60; col. 8, lines 6-67)(see figs. 1D, 2A and 2B).

Applicant respectfully traverses the Examiner's identification of item 110 as a "surgical sponge." To the contrary, Sirimanne denotes numeral 110 in every instance as a "body" (col. 7, lines 62-63; col. 8, lines 8-9) or a "marker" (col. 10, lines 1-2). It is submitted that Sirimanne's "body" or "marker" cannot properly be read as the surgical sponge recited by claim 1. As depicted in Fig. 1D, body 110 is said to include "a number of pores (138) through which tissue may grow" (col. 7, lines 63-64). On the other hand, applicant's usage of the term "surgical sponge" must be governed by the teaching at page 1, lines 19-22 of the specification. Far from being a surgical sponge of the type recited by claim 1, whose removal at the completion of surgery is essential to prevent serious, deleterious consequences (see the specification, e.g. at page 1, line 25 through page 2, line 13), body 110 of Sirimanne is clearly intended to remain indefinitely

within a patient, indeed to be bodily incorporated by the intentional, interpenetrating growth of tissue.

Applicant maintains the position that mere usage of the term "sponge" in Sirimanne is an insufficient predicate for the Examiner's position. Significantly, the term "sponge" or grammatical equivalent thereof appears only 8 times in Sirimanne, specifically at col. 2, line 62 ("collagen sponge"); col. 8, lines 60-64 ("spongy, or expanding gelatinous bioabsorbable materials such as collagen, cross-linked collagen, regenerated cellulose, synthetic polymers, synthetic proteins, and combinations thereof"); col. 9, line 7 ("spongy collagen or cellulose"); col. 9, lines 15-16 ("ACTIFOAM collagen sponge"); col. 11, lines 55-56 ("on or near the surface of the sponge"); col. 11, line 61 ("each individual sponge"); col. 11, line 67 ("perimeter of the sponge body"); and col. 12, line 8 ("ends of the sponge"). Of these references, the first four expressly specify a sponge and the material of which it is made. Significantly, all the disclosed materials are characterized as bioabsorbable. The second four references describe the usage of the sponge, and it is submitted that read in the full context, all the disclosed sponges are therefore bioabsorbable sponges.

On the other hand, applicant clearly distinguishes surgical sponges from bioabsorbable sponges, such as Sirimanne's. Were bioabsorbable sponges to be regarded as surgical sponges, the drastic consequences of sponge retention and the art-recognized definition of the condition of "gossypiboma" (see, e.g. page 2, lines 1-2 of the instant specification) simply never would have arisen.

Conspicuously absent from Sirmanne is any indication that body or marker 110 carries out any of the functions provided by applicant's surgical sponge at page 1, lines 19-22. Applicant's usage is submitted to be entirely conventional, and clear to a person having ordinary skill in the art of surgery. In a pertinent entry, *Merriam Webster's Third International Dictionary-Unabridged* (1993) defines "sponge" as "a small pad made of multiple folds of gauze or of cotton and gauze used to mop blood from a surgical incision, to carry inhalant medicaments to the nose, or to cover a superficial wound as a dressing. *Id.* at 2203. Clearly, even Sirimanne's "sponge" is of an entirely different type than applicant's in both function and composition.

In the August 22 Advisory Action, the Examiner asserts that the words of a claim must be given their plain meaning unless such meaning is inconsistent with the specification. The Examiner further states that the specification does not provide a definition of a surgical sponge that differs from that of a conventional sponge. Applicant respectfully disagrees. The term "sponge" in the present specification is <u>never</u> used in any context in which the modifier "surgical" is not express or implied. Accordingly, it is submitted that the term "conventional sponge," for which the Examiner supplies no difference, may not properly be exchanged for applicant's terms "sponge" or "surgical sponge."

The Examiner has acknowledged that Sirimanne does not expressly disclose the specific X-ray density or size of the markers. However, the Examiner has argued that mere changes in size, weight or shape are not sufficient to patentably distinguish an invention over the prior art. *In re Rose*, 220 F.2d

459, 105 USPQ 237 (CCPA 1955) (Claims directed to a lumber package "of appreciable size and weight requiring handling by a lift truck" were held unpatentable over prior art lumber packages which could be lifted by hand because limitations relating to the size of the package were not sufficient to patentably distinguish over the prior art.); *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976)("mere scaling up of a prior art process capable of being scaled up, if such were the case, would not establish patentability in a claim to an old process so scaled." 531 F.2d at 1053, 189 USPQ at 148.); *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was signficiant).

The Examiner has argued that, in the instant case, it is well known in the art that increased density and size of a barium marker increases its ability to be detected by an X-ray. (see, e.g., Dyer, US Pat. No. 4,639,253, col. 3, lines 4-12). Thus, the Examiner states that, at the time of the invention, it would have been obvious to one of ordinary skill in the art to maximize the size and/or density of a barium sulfate marker in a surgical sponge in order to make it more readily detectable by an X-ray. He has further indicated that making all the markers the same shape would simplify manufacturing.

Applicant respectfully traverses these arguments and submits that the Examiner has not made out a *prima case* of obviousness. It is respectfully

submitted that the subject matter of claims 1-7 and 17 does not merely represent an increase in the density and size of a marker. Further, it is maintained that applicant's amended claims clearly define over Sirimanne. Claims 1-7 and 17, as amended, call for a surgical sponge comprising (i) three substantially spherical radiopaque markers; (ii) said markers being closely grouped and proximate to one another; (iii) each of said markers having an x-ray density equivalent to at least about 0.1 g/cm^2 of $BaSO_4$; and (iv) said radiopaque markers being disposed in a relationship that is substantially fixed both in spacing and in orientation.

Applicant respectfully submits that nowhere does Sirimanne disclose or suggest a surgical sponge comprising three substantially spherical radiopaque markers, the markers being closely grouped and proximate to one another. Even less does Sirimanne disclose a configuration in which such marker elements are also disposed in a relationship that is substantially fixed both in spacing and in orientation. At best, at Fig. 1D, Sirimanne discloses a surgical apparatus having three radiopaque objects, but only one of these objects (150) is substantially spherical, and the apparatus is nowhere said to be a "surgical sponge." Further, the markers (150, 154, 156) at Fig. 1D of Sirimanne are not closely grouped to one another. Even less are they closely proximate. See Sirimanne at col. 8, lines 6-18 which states:

> "A trio of markers is also shown in FIG. 1D evenly aligned along the body longitudinal axis (140). Barb marker (156), spherical marker (150), and ring-shaped marker (154) demonstrate the use of different multiple markers in a single body (110). As previously described, such a design helps a physician to determine the spatial orientation of the inventive device when it is deployed in a biopsy cavity. Although the barb marker (156) is illustrated in a `V` configuration, it is an important aspect of the barb marker (156) to have a shape that is clearly not spherical. This allows the barb marker (156) to be easily distinguished from

calcifications that may be observed during any non-invasive imaging techniques." (emphases added).

In light of this disclosure, it is clear that Sirimanne teaches away from a sponge having three substantially spherical markers, because Sirimanne discloses the need to have a barb marker (156) that is clearly not spherical in order to easily distinguish the marker from calcifications that may be observed during any non-invasive imaging techniques. Therefore, there is clearly no basis to carry out the extensive reconstruction of the three markers in Fig. 1D of Sirimanne that would be required to reach applicant's configuration wherein the markers are substantially spherical and closely grouped and proximate to each other. By way of contrast, the surgical sponge of present claims 1-7 and 17 comprises three substantially spherical markers that are closely grouped and proximate to one another, and therefore produce an x-ray image that is distinctive and easily recognizable.

Moreover, the disclosure cited by the Examiner, Sirimanne's Fig. 1D, clearly shows the markers (150, 154, 156) being completely separate from each other. By way of comparison, present claims 1-7 and 17 require the markers to be closely grouped and proximate to one another, this result having the advantage of displaying an easily detectable image on an X-ray because of the grouping arrangement of the markers in close proximity to one another. Therefore, even assuming arguendo that the three markers in Fig. 1D of Sirimanne were each modified to be substantially spherical, the markers would still not be closely grouped and proximate to one another, as required by present claims 1-7 and 17.

Applicant maintains to the contrary that the Sirimanne teaches away from closely proximate markers. Sirimanne expressly teaches that if his device were modified as required to reach applicant's claimed subject matter, it would be rendered inoperative for carrying out its intended function. Under *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984), an obviousness determination is thereby precluded. See also *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH* ["A prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.'" 139 F.3d 877, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998), quoting *In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994).] and *McGinley v. Franklin Sports, Inc.* ["We have noted elsewhere, as a 'useful general rule,' that references that teach away cannot serve to create a prima facie case of obviousness." 262 F.3d 1339, 1354, 60 U.S.P.Q.2d 1001 (Fed. Cir. 2001) (citing *In re Gurley, supra*)].

The Examiner has countered applicant's argument with respect to the close grouping of the three markers, stating that Sirimanne suggests modifying the markers shapes with a wide variety of possibilities and by asserting that applicant's limitation is a relative limitation and that no definition has been provided that precludes the Examiner's interpretation. While applicant recognizes that terms in claims being examined are to be given a broad reading, it is submitted that such breadth is not without limit, and that the Examiner's assertions are not tenable in light of what would be understood by a person

having ordinary skill in the art reading the instant specification in its entirety. See, e.g., *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321, 1327-29 (Fed. Cir. 2005) (en banc), *cert. denied,* 126 S. Ct. 1332 (2006), which stated that "The claims, of course, do not stand alone. Rather, they are part of 'a fully integrated written instrument,' *Markman*, 52 F.3d at 978, consisting principally of a specification that concludes with the claims. For that reason, claims 'must be read in view of the specification, of which they are a part.' *Id.* at 979...The pertinence of the specification to claim construction is reinforced by the manner in which a patent is issued. The Patent and Trademark Office ('PTO') determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction 'in light of the specification as it would be interpreted by one of ordinary skill in the art.' *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004)."

In the present instance, applicant maintains that "closely grouped and proximate" must be interpreted in light of the teaching of the specification at page 4, lines 8-11, that "The marker has a high radiographic density and a distinctive shape, whereby the marker produces an x-ray image with high contrast and a shape that is readily recognizable and differentiated from the images produced by other items and structures commonly seen in x-rays of post-operative patients." Applicant maintains that a close grouping of three spherical elements provides an especially preferred form of distinctive shape. Significantly, Sirimanne expressly recognizes that spherical shapes taken in isolation would not provide such a distinction, given the likelihood of confusion

with calcifications, e.g. in breast tissue. See col. 8, lines 14-16 quoted above. The benefit of three spherical shapes in close proximity, which is unrecognized by Sirimanne, is submitted to overcome any contention based on Sirimanne's alleged disclosure of a "wide variety of possibilities."

Applicant further points to a central factual predicate of *Dailey*, namely the required absence of persuasive evidence that a particular configuration was significant, for a determination of obviousness to be warranted. However, in the present instance, applicant has provided just such evidence, namely, the recognition that a unique configuration of radiopaque markers provides a signature that markedly enhances the ability of a diagnostician to recognize the presence of a retained surgical article. As a result, the present configuration is no "mere" change in shape. Rather, the present configuration provides a detection capability that is surprising and unexpected, even in light of the references applied.

Other subsequent cases have confirmed that in this context the showing of a solution to a stated problem is significant and results in patentable moment being conveyed by a recited shape that solves the problem. ('The shape of the neck recited in claim 1 is significant in that it solves a stated problem. Under these circumstances and given the foregoing deficiencies in the examiner's prior art evidence, the shape of the neck recited in claim 1 cannot be baldly dismissed as an obvious matter of design choice.' *Ex Parte Moore*, 1996 WL1796237 2 (B.P.A.I. 1996)). Moreover, a reading of *Dailey* as establishing a *per se* rule has been expressly prohibited. ('The examiner, instead, merely relies upon a *per se*

rule that mere changes of shape are obvious. As stated by the Federal Circuit in *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (1995), "reliance on *per se* rules of obviousness is legally incorrect and must cease."' *Ex Parte Hall*, 2001 WL1057294 3 (B.P.A.I. 2001).)"

Furthermore, a number of other disclosures in Sirinamme also teach functions which necessitate the separation of radiopaque elements. Fig. 1B depicts a body in which a longitudinal axis is ascertainable by imaging radiopaque elements 154. But were elements 154 not spatially separated, then the orientation of axis 114 could not be determined. The same considerations apply to Fig. 1D, to which the Examiner has specifically referred. Spatial separation of elements 150, 154, and 156 is again required for the determination of spatial orientation, as taught at col. 8, lines 10-12. An extreme form of this separation is depicted by Figs. 3C and 3D, in which the marking elements are at spatial extremes (either diametrically opposite or at opposite cylindrical ends, respectively) of a structure.

Fig. 1G depicts a device in which a band 154 binds a looped arrangement of bioabsorbable surgical material, which may be flexible and have radiopaque materials. The suture material is taught to be desirably flexible to facilitate expansion of the body in the cavity (col. 9, lines 48-50). It is submitted that such an expansion is inimical to the substantially fixed spacing and orientation and the close grouping of the radiopaque elements required by claim 1.

It is submitted that applicant's surgical sponges, as provided by present claims 1-6 and 17, are more readily and reliably recognizable by a radiologist

viewing an X-ray of the patient's body. The presence of three substantially spherical markers, closely grouped to one another, and disposed in a relationship that is substantially fixed both in spacing and in orientation, results in a unique image that would be highly unlikely to occur under other circumstances attendant a surgical procedure.

Applicant further submits that the substantially spherical shape to the radiopaque markers is significant to the present invention, as claimed. Namely, as stated hereinabove, the substantially spherical configuration of the three closely grouped radiopaque markers allows them to be easily detected on an X-ray film taken of a patient. The substantially spherical shape is a preferred shape because a sphere has the same cross section view from all angles; therefore, no matter what the angle and/or configuration of the sponge when the patient is X-rayed, a spherical image will be easily recognized, especially when a close and proximate group of three substantially spherical markers are contained within the surgical sponge, as required by present claims 1-6, 11, 13-14, and 17-19.

Applicant respectfully submits that Sirimanne does not disclose these limitations, namely, three substantially spherical markers, the markers being closely grouped and proximate to one another. See arguments presented hereinabove. It is submitted that a *prima facie* case of obviousness has not been made out with respect to present claims 1-6.

Regarding claim 17, the Examiner has pointed to Sirimanne's Fig. 1D as allegedly teaching three markers (150, 154, 156) that are contiguous. In the response dated March 5, 2007, applicant cited a dictionary definition for the term

"contiguous" as "being in actual contact : touching along a boundary or at a point" [Merriam-Webster's Medical Dictionary, Merriam-Webster, Inc. 27 Feb. 2007, http://dictionary.reference.com/browse/contiguous.] On the other hand, the Examiner has provided a far less restrictive definition, and has construed the term "contiguous" as being neighboring or adjacent, pointing to definitions provided by *Encarta* and *The Free Dictionary by Farlex*, asserting that under MPEP 2111.01, terms must be given their "plain meaning" unless such meaning is inconsistent with the specification. He has further alleged that the specification does not provide a definition of "contiguous" that is contrary to elements that are neighboring or adjacent.

Applicant respectfully submits that the foregoing statement is not reconcilable with the controlling law established by the Federal Circuit in *Phillips v. AWH Industries*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) (*en banc*). The court's ruling establishes that an inventor's own lexicography must control the construction of claims that use terms expressly defined in the specification. Applicant's express definition is also to be dispositive in the construction given the claims during the examination process in the USPTO. *In re Johnston*, 435 F.3d 1381, 1384, 77 USPQ2d (BNA) 1788, 2006 US App. LEXIS 2282, slip. op. at 4 (Fed. Cir. 2006). See also *Toro Company v. White Consolidated Industries, Inc.*, 199 F.3d 1295, 1301, 53 U.S.P.Q.2d (BNA) 1065, 1069 (Fed. Cir. 1999) (holding that the meaning of words used in a claim is not construed in a "lexicographic vacuum, but in the context of the specification and drawings").

In the present instance, the term "contiguous" recited in claim 17 finds direct correspondence in the specification at page 15, line 24, to page 16, line 1, which describes marker 48 of Fig. 10 as comprising "a plurality of closely proximate or contiguous spheres 50." Such a situation is clearly congruent with the definition cited by applicant. Far from arising in claim 17 from a lexicographic vacuum, the term "contiguous" has a clear antecedent context in both the specification and the drawings, and from base claim 1. Accordingly, it is submitted that any arbitrary selection of dictionary definitions is improper, first recourse being instead to the teaching of the specification taken as a whole. Instead, any definition used in claim construction must comport with the full specification context. By virtue of the dependency of claim 17 from claim 1, the use of "contiguous" must be construed in a manner that further specifies and restricts claim 1's configurational requirements that the markers be "closely grouped and proximate to one another" and "disposed in a relationship that is substantially fixed both in spacing and in orientation." In addition, the configuration must be such as to produce an x-ray image having a distinctive, visually recognizable shape.

Applicant respectfully submits that the Examiner has construed "contiguous" in a manner that is broader than what would be understood by a skilled artisan in light of applicant's full disclosure. In particular, the Examiner has cited the Encarta definition of "contiguous" as meaning "neighboring or adjacent," thereby selectively omitting important qualifications from the original. While the Encarta definition admittedly includes the words "neighboring" and

"adjacent," they are specifically and further qualified. The first definition is "adjoining: sharing a boundary or touching each other physically;" the second is "neighboring: situated next to something else or to each other." The Free Dictionary definition provides similar qualifications: "(1) Sharing an edge or boundary touching; (2) Neighboring, adjacent; (3a) Connected without a break; (3b) Connected in time, uninterrupted." All these definitions include a common thread of describing elements that are close, and in most cases, functionally in contact with each other. They preclude an arrangement in which there are significant intervening structures. This common element directly reflects applicant's language at page 15, line 24, and in claim 1, which both emphasize close proximity or actual contact between the elements, as well as the definition cited above.

By way of marked contrast, the Sirimanne reference is directed to marking a spatially extended biopsy cavity to delimit its ultimate boundaries. The cavity is marked by a body of a resilient, preferably bioabsorbable material (col. 2, lines 54-57). The marking function demands that the body retain integrity and be detectable for an extended, if not an indeterminate, period of time (col. 3, lines 27-31; col. 4, lines 23-30). This behavior contrasts with applicant's surgical sponge, which is intended to be within a patient only for the relatively short duration of a surgical procedure. Removal thereafter is essential to prevent serious, and potentially fatal, consequences.

In view of the foregoing remarks, it is respectfully submitted that the subject matter of presently amended claims 1-6 and 17 is not disclosed or suggested by Sirimanne.

Accordingly, reconsideration of the rejection of claim 1-7 and 17 under 35 U.S.C. § 103(a) as being unpatentable over Sirimanne is respectfully requested.

Claim 11 was rejected under 35 USC § 103(a) as being unpatentable over Sirimanne as applied to claims 1-7 above, and further in view of Ishikawa et al. (US 6,366,206; hereinafter "Ishikawa").

Ishikawa el al. disclose a method and apparatus for attaching one or more transponders to medical and non-medical products to tag respective ones of the products with identifying data contained in a memory of the transponders. The one or more transponders each include a memory containing the corresponding identifying data which is emitted by the respective transponder in response to an electromagnetic signal emitted externally of the transponder. The identifying data corresponds to at least one of the respective one or more transponders and a respective product for tagging. The one or more transponders are attached to respective ones of the products to tag the products with the corresponding identifying data.

Applicant respectfully submits that nothing in Ishikawa et al. cures the lack of disclosure or suggestion in Sirimanne of the configuration of radiopaque marker elements delineated by amended claim 1, from which claim 11 depends. The Examiner has not pointed to any subject matter in Ishikawa et al. that

pertains to the features of claim 1. Applicant thus maintains that claim 11, being dependent from claim 1, is thus patentable for at least the same reasons set forth above.

Further, applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness for claim 11. In particular, the Examiner has not pointed to any basis in the prior art to suggest the claimed combination of the two types of marking technologies, as called for by present claim 11. Instead, applicant submits that such combination is only found by hindsight reasoning and/or applicant's own disclosure. *See* MPEP 2142 *et seq.* Significantly, the combination of the two types of marking technologies provides a synergistic improvement in the probability that a surgical item is detected before it causes serious bodily harm not recognized heretofore.

Accordingly, reconsideration of the rejection of claim 11 under 35 USC §103(a) as being unpatentable over Sirimanne in view of Ishikawa et al. is respectfully requested.

Claims 13, 14, 18, and 19 were rejected under 35 USC §103(a) as being unpatentable over Sirimanne as applied to claims 1-7 above, and further in view of *Uncommon Peril of Forgotten Surgical Tools*, Denise Grady, The New York Times, Jan. 21, 2003 (hereinafter "*Uncommon Peril*").

The Examiner acknowledges that Sirimanne does not disclose expressly disclose the steps of x-raying a patient and removing a surgical sponge thereafter. However, the Examiner states that *Uncommon Peril* teaches that a patient

suspected of having a surgical sponge or other implement having a marker inside them can be x-rayed and if the implement is found to be there, it can be removed.

Applicant respectfully submits that present claims 13, 14, 18, and 19, as amended, patentably define over Sirimanne in view of *Uncommon Peril*. Applicant respectfully submits that the arguments set forth above in connection with the rejection of claims 1-7 and 17 over Sirimanne apply with equal force to claims 13, 14, 18, and 19. Clearly, *Uncommon Peril* does not pertain to any configuration of radiopaque elements comprising three closely grouped spherical elements, and so, even in combination, does not cure the deficiencies of Sirimanne delineated above. Applicant thus maintains that there is no prior art that discloses or suggests a method of detecting a surgical sponge within a surgical patient, said surgical sponge comprising three substantially spherical radiopaque markers, said markers being closely grouped to one another, each of said markers having an x-ray density equivalent to at least about 0.1 g/cm^2 of $BaSO_4$, said radiopaque markers being disposed in a relationship that is substantially fixed both in spacing and in orientation, and said method comprising the steps of: (a) obtaining at least one x-ray of at least a portion of said patient likely to contain said radiopaque markers; and (b) examining said x-ray to detect and locate an image of said sponge.

Accordingly, reconsideration of the rejection of claims 13, 14, 18, and 19 under 35 USC §103(a) as being unpatentable over Sirmanne in view of *Uncommon Peril* is respectfully requested.

CONCLUSION

In view of the amendments to the claims and the remarks set forth above, it is respectfully submitted that the present application is in allowable condition. Reconsideration of the rejection and allowance of claims 1-6, 11, 13-14, 17-19, as amended, are earnestly solicited.

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